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World Health Organization

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Agenda Item 5 **NFSDU/40 CRD 28**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Fortieth Session

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REPORT OF THE PHYSICAL WORKING GROUP ON THE PROPOSED DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS

(Prepared by South Africa, Senegal and Uganda)

Background

The pWG met prior to CCNFSDU40 to further discuss the proposed draft guidelines for RUTF taking into account the conclusions and recommendations of the electronic working group and the comments received prior to CCNFSDU40. The Chair introduced the topic and highlighted key aspects of the guidelines that the pWG should focus on referring to the agenda paper CX/NFSDU. 18/40/6 and CRD16. Sixteen recommendations were discussed. The proposed changes to the texts and recommendations made by the pWG are highlighted in bold and deleted in strike-through format.

1. Basic Raw Materials and Ingredients

1.1 Legumes and Seeds

There was widespread support for the proposed texts on legumes and seeds by the pWG members. The pWG also agreed that the texts reflected with strikethrough on treatment of raw materials should be moved to Section 8 of the guidelines.

Recommendation 1

That CCNFSDU agree to the following texts on Legumes and Seeds:

Legumes and Seeds

Legumes and seeds such as soybeans, lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and seeds must comply with the relevant Codex Alimentarius texts when used in the manufacturing of RUTF.

Legumes and ~~pulses~~ seeds must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutinins), trypsin, ~~and~~ chymotrypsin inhibitors and **phytoestrogens**.

~~[Lectins can be reduced by moist heat treatment. Trypsin inhibitor activity may be reduced to acceptable levels by heating to high temperatures or by prolonged boiling. Phytate can be reduced enzymatically or by soaking or fermentation. Phytoestrogens can be reduced by fermentation.~~ **Field beans or Faba beans (Vicia faba L) should not be used in the formulation of RUTF because of the danger of favism**~~]~~.

1.2 Vitamins and Minerals

The pWG agree on the text in CRD 16 section 5.1.55 for vitamins and minerals, with the addition of the text in bold below.

Recommendation 2

That CCNFSDU agree to the proposed texts on Vitamins and Minerals:

~~[~~Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic salts of minerals that are insoluble or requiring an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that leads to a moderate excess of non metabolisable base. The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride.~~]~~

All added ~~[micronutrients]~~/ ~~[~~vitamins and minerals~~]~~ must be in accordance with the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979). Examples of ~~vitamin and~~ mineral forms for RUTF formulation can be found in the *WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999*). **[The amount of** ~~[micronutrients]~~/ ~~[~~vitamins and minerals~~]~~ **added to achieve the target level must be adjusted based on the chemical form, interaction, and impaired absorption with other nutrients and non-nutrients and scientific evidence showing adequate stability and bioavailability in the finished product**.~~]~~

1.3 Other Ingredients

1.3.1 Available Carbohydrates

A footnote was proposed to be included in the guidelines. With regard to the proposed footnote on available carbohydrates, CCNFSDU39 proposed that a statement which could read "*Any carbohydrate added for sweetness should be used sparingly*" should be included in the footnote.

Several Members were of the view that the addition of free sugars in RUTF should be reduced and be aligned with the WHO recommendation. The WHO Representative reiterated that the 2015 Guidelines[1] were meant for the general population and do not apply to individuals in need of therapeutic diets, including for the management of severe and moderate acute malnutrition. A Member informed the delegates that the addition of free sugar in RUTF formulation is approximately 15% of total energy.

Several Members had divergent views on the proposed texts with specific reference to the sentence on "Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children", since there was no scientific justification. Several members raised the potential adverse effects such as osmotic diarrhea and opportunistic infections such as oral candida that may be a risk for SAM children consuming RUTF. The WHO Representative raised a concern about the inclusion of the word "sparingly" in the proposed footnote due to various interpretations by Member States and difficulties in implementing such vague recommendations. The pWG couldn't reach consensus on the proposed texts and it was agreed to leave the texts in square brackets for Committee's consideration. Some members suggest that the footnote could be incorporated into the main text.

Recommendation 3

That CCNFSDU agree to the proposed texts on available carbohydrates

Available Carbohydrates[6]

[Carbohydrates are used to achieve energy requirements in balance with proteins and lipids. The palatability of the RUTF can be increased by the addition of available carbohydrates. Available carbohydrates must adhere to the relevant Codex Alimentarius texts.

Honey should not be used in RUTF due to the risk of infant botulism from *Clostridium botulinum*.

[6)]Sucrose, plant starch, maltodextrin, **lactose** ~~should be~~ **are** the preferred carbohydrates in RUTF. ~~[the carbohydrate composition should be such that it does not increase the risk of osmotic diarrhea in SAM children)~~] Only precooked and/or gelatinized starches ~~[gluten-free]~~ ~~by nature~~ may be added. ~~Additional Mono and disaccharides should be used sparingly.~~[**Any carbohydrate/free sugar added for sweetness ~~intake acceptability /palatability~~ should be used sparingly]**.

1.4 The Use of other Matrices in RUTF formulation

A Member raised that RUTF were not foods for *special medical purposes* and instead belong to *foods for special dietary uses* and that therefore reference Section 3 of the CXS 180-1991 in the proposed texts would not be appropriate. The pWG Members reiterated that RUTFs were foods for special medical purposes, therefore it was agreed they should be subjected to the provisions laid down in section 3 of CXS 180-1991. It was agreed that the additional proposed texts be deleted since it was a repetition of the texts in section 3 of CXS 180-1991, which is already referenced in the proposed texts. The pWG agreed to the proposed texts.

Recommendation 4

That CCNFSDU agree to the proposed texts which reference Section 3 of the CXS 180-1991 on the use of other matrices in RUTF formulations as follows:

The Use of other Matrices in RUTF Formulation

[1] Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015.

RUTF may be manufactured with formulations different from the one laid down in these guidelines provided that these formulations comply with Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991).~~, [particularly regarding their use that should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.]~~

2. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

The nutritional composition recommended in the '2007 Joint statement by UN agencies' was used as a basis for reviewing the nutritional composition of RUTF.

2.1 Energy

There was agreement amongst pWG Members on the current energy values of 520 to 550 kcal/100g as stipulated in the 2007 Joint Statement, and the proposed texts on energy.

Recommendation 5:

That CCNFSDU agree to the proposed text on energy and the energy values as follows:

Energy

Draft Text

The energy density of the formulated RUTF should be between 5.2 - to 5.5 kcal per gram. The energy density of RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates) and/or processing the basic raw materials and ingredients as indicated in Section 8.

Energy Values

Unit	Minimum	Maximum	GUL
g/100g	5.2	5.5	-
Kcal/100g	520	550	-

2.2 Proteins

There was agreement amongst the PWG Members on the current recommendations that protein should provide 10%-12% of the total energy, and kcal/100g not to be included.

Recommendation 6:

That CCNFSDU agree to the proposed protein values in RUTF.

Protein should provide ~~[(52kcal/100g – 66/100g)]~~ 10%-12% of the total energy.

Unit	Minimum	Maximum	GUL
g/100g	~~12.8~~ 13	~~16.2~~ 16.5	-
g/100kcal	~~2.3~~ 2.4	~~3.1~~ 3.2	-

2.3 Lipids

The pWG Members agreed to maintain the current values as stipulated in the 2007 UN Joint Statement of the fat contribution to the total energy of between 45% and 60%.

Recommendation 7:

That CCNFSDU agree to the proposed text on fats/lipids and the proposed minimum and maximum fats/lipids values as follows:

Lipids

Lipids should provide 45% to 60% of the total energy.

Unit	Minimum	Maximum	GUL
g/100g	~~26~~ 25.8	~~37~~ 36.3	-
g/100kcal	~~5~~ 4.7	~~6.7~~ 7	-

2.3.1 Essential Fatty Acids

Some members of the pWG highlighted that the high levels of linoleic acid (omega 6) in the current RUTF may result in poor conversion of alpha linolenic acid (omega 3) into DHA, due to competition for enzymes pathways during metabolism. Based on current evidence the ratio of 1:1 of ALA:LA seems to produce the most optimal DHA levels in SAM children. Therefore, the linoleic (LA) acid in the lower part of the permitted range would be preferable.

Several pWG Members were in favour of deleting the text on ALA:LA ratio in RUTF formulation for SAM children, in favour of absolute values. There was an agreement amongst the pWG on the proposed n-6 fatty acids and n-3 fatty acids as stipulated in the 2007 Joint Statement.

Recommendation 8:

That CCNFSDU agree to the proposed text on essential fatty acids and the proposed minimum and maximum n-3 and n-6 fatty acids values as follows:

Lipids

The level of linoleic acid should not be less than 333mg ~~316~~ mg per 100 kcal and shall not be more than 1110 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal [~~and shall not be more than 280 mg per 100kcal.] The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 1:1 and 15:1.~~

n-6 Fatty acids

Unit	**Minimum**	**Maximum**	**GUL**
Kcal/100kcal	**3**	**10**	**-**
~~mg/100g~~	~~3 1731.6~~	~~10 6111~~	-
mg/100kcal	~~576.9~~ 3333	~~1818.2~~ 1110	-

n-3 Fatty acids

Unit	**Minimum**	**Maximum**	**GUL**
Kcal/100kcal	**0.3**	**2.5**	**-**
~~mg/100g~~	~~0.3 172~~	~~2.5 1529~~	-
mg/100kcal	~~57.69~~ 33	~~454.5~~ 280	-

3. Vitamins and minerals

The pWG discussed the proposed minimum, maximum and GUL values on vitamins and minerals in Annex "Nutrition Composition for RUTF". The pWG also agreed to including some introductory text on vitamins and mineral.

Recommendation 9:

That CCNFSDU agree to the proposed introductory text on vitamins and minerals :

RUTF should contain the vitamin and minerals presented in the annex : Nutrition Composition for RUTF following minimum and maximum or guidance of upper values in the annex.

3.1. Vitamins

3.1.1 Vitamin A

The maximum value of vitamin A of 1.2 mg RE/100g and its accompanying footnote was agreed on in order to account for vitamin A's instability and its degrading effect during the long shelf life of the product.

Recommendation 10:

That CCNFSDU agree to the minimum, maximum and associated footnote for vitamin A as follows:

Unit	Minimum	Maximum	GUL
mg RE/100g	0.8	~~[1.1] OR~~ [1.2]	-
mg/ RE/100kcal	0.15	~~[0.2] OR~~ [0.22]	-
[2]µg RE/100kcal	150	~~[200] OR~~ [220]	-

[2] 1µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

3.1.2 Vitamin D

The maximum value of vitamin D of 22 µg/100 g and its accompanying footnote was agreed on in order to account for vitamin D's raw material variability, degradation during shelf life of the product. The forms of vitamin D were not discussed in the pWG.

Recommendation 11:

That CCNFSDU agree to the minimum, maximum/GUL and associated footnote for vitamin D as follows:

Unit	Minimum	Maximum	GUL
[3] µg/100 g	15	~~[20] OR~~ [22]	[30]
[3] µg100 kcal	2.7	~~[3.6] OR~~ [4]	-

[3] 1 µg cholecalciferol = 40 IU vitamin D [two forms of vitamin D are allow in RUTF formulation are cholecalciferol (D3) and ergocalciferol(D2).]

3.1.3 Vitamin E

Recommendation 12:

That CCNFSDU agree to the minimum and associated footnote for vitamin E as follows:

Unit	Minimum	Maximum	GUL
[4] mg/100 g	20	-	-
[4] mg α-TE /100 kcal	4	-	-

[4] 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)

[4] 1 mg α-tocopherol =2.00 mg *all-rac*-α-tocopherol (dl- α-tocopherol)

3.1.4 Other Vitamins

There was ~~widespread~~ agreement amongst the pWG Members to retain the current values on vitamin E, vitamin K, vitamin B1, vitamin B2, vitamin C, vitamin B6, vitamin B12, folic acid, niacin, pantothenic acid and biotin as stipulated in the 2007 Joint Statement.

Recommendation 13:

That CCNFSDU agree to the following recommendations for vitamin E, vitamin K, vitamin B1, vitamin B2, vitamin C, vitamin B6, vitamin B12, folic acid, niacin, pantothenic acid and biotin for RUTF as follows:

Vitamin E

Unit	Minimum	Maximum	GUL
[4] mg/100 g	20	-	-
[4] mg α-TE /100 kcal	~~4~~3.84	-	-

[4] 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)

[4] 1 mg α-tocopherol =2.00 mg *all-rac*-α-tocopherol (dl- α-tocopherol)

Vitamin K			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	15	30	-
µg/100 kcal	2.9	5.5	-
Vitamin B1			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	0.5	-	-
mg/100 kcal	0.1	-	-
Vitamin B2			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	1.6	-	-
mg/100 kcal	0.3	-	-
Vitamin C			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	50	-	-
mg/100 kcal	9.6	-	-
Vitamin B6			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	0.6	-	-
mg/100 kcal	0.12	-	-
Vitamin B12			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	1.6	-	-
µg/100 kcal	0.3	-	-
Folic Acid			
Unit	**Minimum**	**Maximum**	**GUL**
[5] µg/100 g	200	-	-
[5] µg/100 kcal	38.5	-	-
[5] 1 µg of folic acid = 1.7 µg of Dietary Folate Equivalents (DFE)			
Niacin			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	5	-	-
mg/100 kcal	1	-	-
Pantothenic Acid			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	3	-	-
mg/100 kcal	0.6	-	-
Biotin			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	60	-	-
µg/100 kcal	11.5	-	-

3.2 Minerals

There was ~~widespread~~ agreement amongst the pWG Members to retain the current values on the minerals as stipulated in the 2007 Joint Statement with the exception of the maximum values on potassium, calcium and magnesium were increased to allow for variability in raw materials. A member raise the suggestion of including a ratio of phytic acid to iron and zinc however the pWG agreed not to include such a ratio in this section as it will be addressed by section 8 of the proposed guidelines.

Recommendation 14:

That CCNFSDU agree to the following recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine.

Sodium

Minimum	Maximum	GUL
-	290	-
-	53	-

Potassium

Minimum	Maximum	GUL
1,100	~~1,400~~ 1,600	-
212	~~255~~ 287	-

Calcium

Minimum	Maximum	GUL
300	~~[600] or~~ 785	-
58	~~[109] or~~ [143~~]~~	-

Phosphorus

Minimum	Maximum	GUL
300	~~[600] or~~ 785	-
58 57.6	~~[109] or~~ [143]	-

Magnesium

Minimum	Maximum	GUL
80	~~[140] or~~ 235	-
15.4	~~[26] [~~25.4~~] or [43] [~~42.7~~]~~	-

Iron

Minimum	Maximum	GUL
10	14	-
1.9	2.6	-

Zinc

Minimum	Maximum	GUL
11	14	-
2	2.6 2.5	-

Copper

Minimum	Maximum	GUL
1.4	2	-
0.27	0.33	-

Selenium

	Minimum	Maximum	GUL
	20	40	-
	4 3.84	7 7.3	-

Iodine

	Minimum	Maximum	GUL
	70	160	-
	13.46 13.5	25.5	-

Moisture Content

	Minimum	Maximum	GUL
Percentage(%) [Water activity (aW)]	0.2	~~2.5~~ 0.45	-

4.0 Protein quality assessment in RUTF

A representative from FAO made a presentation to the pWG on the recommendations of the expert working group on Protein Quality Assessment on Follow up Formula for Young Children and Ready to Use Therapeutic Foods, 2018. The expert report recommended the use of PDCASS in defining the protein quality in RUTF.

There were divergent views on whether to retain or remove the statement "at least 50% of protein is provided by milk products" and whether an additional statement is needed to capture the evidence requirement of new formulations and future innovations that do not contain 50% dairy sourced proteins. The pWG could not agree on to retain or remove the square brackets on the statement "at least 50% of protein is provided by milk products" or the additional statement on evidence on efficacy of the new formulations without dairy proteins.

Based on the expert report the pWG agreed in principle to include the PDCASS method in the determination of the quality of protein in RUTF, and its recommend score for RUTF. The pWG could not reach consensus on the proposed text for protein that should be included in the guideline.

Recommendation 15:

a) That CCNFSDU agree to include PDCASS method in the determination of the quality of protein in RUTF, and its recommend score for RUTF.

b) That CCNFSDU consider the proposed text on protein quality as laid out in the protein expert report:

["at least 50% of protein is provided by milk products"] [**OR a high quality protein source which has the PDCASS score of 100,]**

[The protein quality should be determined using PDCASS score of between 90-100. The efficacy of new formulations should not rely on protein quality considerations alone, and should be tested for their ability to support catch up growth in the target population, which in this scenario would be children of 0.5-4.9 years for RUTF]

[Footnote: A high quality protein source will have a PDCASS score of 100. However, a PDCASS score of >90 can still be considered adequate for these formulations. In formulations with PDCASS score of <90 the quality of protein should be adjusted to achieve the desired value.]

5. Contaminants

UNICEF representative presented an expert report in appropriate criteria and limits for contaminants in Ready to Use Therapeutic Foods (RUTF). The pWG agreed to the recommendations in the report to reference the existing codex standards and codes of practice throughout the RUTF guideline.

Recommendation 16

It is recommended that the products covered by the provisions of these guidelines and the ingredients used in such products comply with the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CAC/MRL 2-2015) and Codex Maximum Residue Limits for Pesticides. **Further guidance is given by codex Codes of practice and should be adhered to.**

6.0 Food Additives

The pWG had divergent views on how to handle food additives in RUTF.

There was agreement that the section on food additives should make reference to the existing Codex standards.

The PWG agreed that the stepwise approach should be continued and should include the identification of the food category under which RUTF falls within the GSFA. Furthermore, the Committee should provide the technological justification for the identified food additives in RUTF.

Recommendation 17

That CCNFSDU continue with the stepwise approach to finalize food additives in the formulation of RUTF.

The pWG did not discuss the following recommendations due to time constraints:

- Preamble
- Processing technologies
- Good manufacturing practices and good hygiene practices
- Methods of analysis and sampling
- Packaging
- Labelling